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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,554	03/15/2006	Jeremy Marshall	30031171	9236

466 7590 12/20/2006  
YOUNG & THOMPSON  
745 SOUTH 23RD STREET  
2ND FLOOR  
ARLINGTON, VA 22202

EXAMINER
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GETTMAN, CHRISTINA DANIELLE

ART UNIT	PAPER NUMBER
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3734

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/20/2006	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/567,554

Applicant(s)

MARSHALL ET AL.

Examiner

Christina D. Gettman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 8 and 9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 10-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 February 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>02/08/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Specification***

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT.
- (e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC.
- (f) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (g) BRIEF SUMMARY OF THE INVENTION.
- (h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (i) DETAILED DESCRIPTION OF THE INVENTION.
- (j) CLAIM OR CLAIMS (commencing on a separate sheet).
- (k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

***Claim Rejections - 35 USC § 112***

Claims 8 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeVaughn et al. (U.S. Patent No. 5,954,738) in view of Kammerer et al. (U.S. Patent No. 6,152,935). LeVaughn et al. disclose the invention substantially as claimed including a lancet having a body (ref. 12, Fig. 3), a drive head (ref. 32, Fig. 3), a projecting needle (ref. 34, Fig. 3), and two sets of compressive springs along the side of the lancet (ref. 50, Fig. 3). LeVaughn et al. do not disclose webs of undulating form that act as springs. Kammerer et al. teach a web of undulating form for the purpose of acting like a spring (Fig. 2A). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified LeVaughn et al. with webs of undulating form in order to allow the needle to retract back into the casing after use. Applicant states in claim 2 that the undulations are out of phase with one another. It would have been obvious matter of design choice to modify two webs being in phase

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with one another to being out of phase with one another, since the applicant does not state that the webs being out of phase with one another solves any stated problem or is for any particular purpose and it appears that the webs would perform equally well with being out of phase with one another.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeVaughn et al. and Kammerer et al. as applied to claim 1 above, and further in view of Ruppert (U.S. Patent No. 6,053,930). LeVaughn et al. and Kammerer et al. disclose the invention substantially as claimed except for a removeable cap attached to a lancet head with flanges (ref. 84, Fig. 1). Ruppert teaches a removeable cap attached to a lancet head with flanges for the purpose of limiting accidental exposure of a needle. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified LeVaughn et al. and Kammerer et al. with a a removeable cap attached to a lancet head with flanges in order to prevent exposure of a needle prior to use.

Claims 5, 6, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over LeVaughn et al. and Kammerer et al. as applied to claim 1 and 2 above, and further in view of Levin et al. (U.S. Patent No. 6,168,606). LeVaughn et al. and Kammerer et al. disclose the invention substantially as claimed except for a lancet holder with a casing, a drive spring, a flange on a movable rib, a flexible button, and a removable cap. Levin et al. teach a lancet holder with a casing (ref. 23, Fig. 10) for the purpose of containment, a drive spring (ref. 50, Fig. 6) for the purpose of pushing the needle, a flange on a movable rib (ref. 71, Fig. 10) for the purpose of moving the

needle, a flexible button (ref. 61, Fig. 4) for the purpose of activating the device, and a removable cap (ref. 90, fig. 3) for the purpose of protecting the needle. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified LeVaughn et al. and Kammerer et al. with a lancet holder with a casing in order to hold the lancet device, a drive spring in order to allow the needle to move out of the housing and pierce tissue, a flange on a movable rib in order to release the needle and allow the drive spring to push the needle forward, a flexible button in order to activate the device and allow the flange to detach from the rib, and a removable cap in order to protect the needle from accidentally puncturing.

Claim 7 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levin et al. as applied to claim 5 above, and further in view of Ruppert. Levin et al. disclose the invention substantially as claimed except for a removeable cap attached to a lancet head with flanges. Ruppert teaches a removeable cap attached to a lancet head with flanges for the purpose of limiting accidental exposure of a needle (ref. 84, Fig. 1). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Levin et al. with a a removeable cap attached to a lancet head with flanges in order to prevent exposure of a needle prior to use.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina D. Gettman whose telephone number is 571-272-3128. The examiner can normally be reached on Monday-Friday 8:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on 571-272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CG



Christina Gettman  
Art Unit 3734  
571-272-3128



MICHAEL J. HAYES  
SUPERVISORY PATENT EXAMINER